

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR2005/000416	International filing date (day/month/year) 23.02.2005	Priority date (day/month/year) 27.02.2004
International Patent Classification (IPC) or national classification and IPC INV. C07K14/76 C07K14/765		
Applicant LABORATOIRE FRANCAIS DU FRACTIONNEMENT ... et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 23.12.2005	Date of completion of this report 18.07.2006
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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR2005/000416

## I. Basis of the report

1. This report has been drawn on the basis of (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

☐ the international application as originally filed.

☒ the description, pages 1-30, as originally filed,  
 pages \_\_\_\_\_, filed with the demand,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the claims, Nos. 1-23, as originally filed,  
 Nos. \_\_\_\_\_, as amended under Article 19,  
 Nos. \_\_\_\_\_, filed with the demand,  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the drawings, sheets/fig 1/6-6/6, as originally filed,  
 sheets/fig \_\_\_\_\_, filed with the demand,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/fig \_\_\_\_\_

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-23	YES
	Claims		NO
Inventive step (IS)	Claims	1-23	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims		NO

## 2. Citations and explanations

## Point V

Statement related to Novelty , Inventive Step, and Industrial Application.

Reference is made to the following documents:

D1: EP-A- 0 498 133;

D2: EP-A-1 329 461;

D3: EP-A-1 329 460;

D4: WO-A-9600237;

D5: Biologicals 29(1), 2001, pages 17-25.

1) D1 mentions a solution (example 1) wich corresponds to parameters of claims 15-23 and which is used for a relevant aim. The resulting solution is not virally safe.

D2 (example 1) describes a solution constaining albumin and which corresponds to abovementioned parameters.

D3 (example 3) describes an albumin solution which is not virally safe.

Consequently, claims 15-23 are novel according to Art. 33(2) PCT.

D4 (see examples 12 and 19) and D5 describe processes based upon nanofiltration at ambient temperature on filters having appropriate porosity and parameters corresponding to other parameters indicated in claims 1-14. The difference between D4 disclosure and that of the present application is, although a nanofiltration step is performed, the filters employed have a cut-off much more lower than those of the nanofiltration filters.

D5 uses the same nanofiltration membranes as those used in the present application in claims 1-14. However, the starting solution is not aqueous, said solution containing a detergent and mouse brain homogenate.

Thus, said claims 1-14 are novel with regard to Art.33(2) PCT.

On the basis of D1-D3, considered as being the closest prior art, the problem to be solved of claims 15-23 is identified as being the preparation of a virally safe albumin aqueous solution. The step of viral safety is not suggested in D1-D3 prior art, said step being however somewhat suggested. It is always questionable that the solution resulting from the immediate application of teachings of D5 to any of the documents D1-D3 could lead to the preparation of a virally safe albumin solution having at the same time the transport and binding sites of therapeutically active ingredients available.

Consequently, claims 15-23 involve an inventive step with regard to Art. 33(3) PCT.

On the basis of D4-D5, considered as being the closest prior art for claims 1-14, the problem to be solved of claims 1-14 is considered as being to provide a process allowing to obtain a virally safe albumin. It is not considered that D4 contains a teaching that would suggest the application of nanofiltration for removing virus to an albumin aqueous solution presenting a low level of salts.

Consequently, claims 1-14 involve an inventive step with regard to Art. 33(3) PCT.

Claims 1-23 are considered as being susceptible of industrial application defined by Article 33(4) PCT.